

### **AMENDMENT TO THE DRAWINGS**

In Fig. 1, please change the location of the lead line for reference numeral 24, as indicated in the attached Replacement Sheet 1/18.

In Fig. 3, please change the location of the lead line for reference numeral 26 (two times), and add reference number 30, as indicated in the attached Replacement Sheet 2/18.

In Fig. 5B, please change reference numeral "46" to "30," as indicated in the attached Replacement Sheet 3/18.

Please add Figs. 12 to 23, as indicated in the attached New Sheets 10/18 to 18/18.

**REMARKS**

The Specification has been amended and new drawings have been added (New Sheets containing Figures 12 to 23) to incorporate material from United States Patent Application Serial No. 10/271,334, filed October 15, 2002 (now United States Patent No. 6,960,217). Priority has been claimed to United States Patent Application Serial No. 10/271,334, and has therefore been incorporated by reference.

According to 37 C.F.R. § 1.57, a copy of the prior filed application accompanies this amendment. The copy has been highlighted to show where the material incorporated by amendment can be found in United States Patent Application Serial No. 10/271,334. The material being inserted was previously incorporated by reference, and the amendment contains to new matter.

The following table additionally correlates the amendments to the material in Serial No. 10/271,334.

<b>Amendment to the Instant Application</b>	<b>Material Location in SN 10/271,334</b>
Specification beginning on page 8, following line 15 (Description of New Drawings)	Page 6, line 32 to Page 7, line 9 Page 7, line 20 to Page 8, line 6
Specification beginning on page 9, line 15	Page 5, lines 1 to 7 Page 5, lines 10 to 14 Page 5, line 17 to Page 6, line 13 Page 8, line 35 to Page 9, line 21 Page 9, lines 31 to 35 Page 10, lines 6 to 32 Page 11, lines 1 to 17
New Figs. 12 to 23	Figs. 6; 7; 8; 9; 14; 14A; 15; 16; 17; 18; 19; 20; 21, respectively

Replacement Sheets for Figures 1; 3; and 5B are also attached, reflecting corrections to the drawing informalities noted by the Examiner. The Specification has also been amended to correct the typographical errors of reference numbers citations "32" and "42." The Specification has also been amended to refer to trademarked materials in accordance with the Examiner's suggestions.

Claims 1 to 22 and 24 to 26 have been canceled. New claims 28 to 30 have been added. Claims 23 and 27 have been amended.

Claims 23 and 27 to 30 remain in the application. Of these, claim 23 is the sole independent method claim.

The claims are generally patterned on the issued claims of US 6,960,217 (from which material has been incorporated by reference), as well as the claims pending in United States Patent Application Serial No. 11/166,411 (filed June 24, 2005) and United States Patent Application Serial No. 11/540,427 (filed September 29, 2006), which are divisional applications based upon US 6,960,217 and therefore contain the same materials. For the sake of completeness, a Supplemental Information Disclosure Statement accompanies this amendment, making of record in this case the documents that are of record in US 6,960,217.

The amended claims differ from the claims of US 6,960,217 and the above-identified divisional applications in that the instant claims define a prosthesis comprising a trunk including a prosthetic material and a scaffold that supports the prosthetic material to define a lumen within the trunk, the trunk including a main body region and a fastening region configured differently than the main body region for the receipt and retention in the second region of at least one tissue-piercing fastener implanted into tissue by an external fastener attachment assembly. The amended claims further define a method that includes (a) the deployment the prosthesis at a target site in an aorta where the diseased or damaged section exists; (b) the introduction of an intraluminal directing device from a remote access site to a location within the prosthesis, the intraluminal directing device including a deflectable distal region; (c) the establishment of a path to the fastening region of the prosthesis by manipulating the intraluminal directing device within the prosthesis to orient the distal region with respect to the fastening region; (d) the introduction from an intraluminal fastener applier, that is introduced along the path established in (c), at least one tissue-piercing fastener into tissue through the fastening region to anchor the prosthesis; (e) the establishment of a path to a different location on the fastening region of the prosthesis by manipulating the intraluminal directing device within the prosthesis to orient the distal region with respect to the different location; (f) the introduction from an intraluminal fastener applier, that is introduced through the path established in (e), at least one tissue-piercing fastener into tissue at the different location to

further anchor the prosthesis; and (g) the repetition of (e) and (f) until a desired plurality of tissue-piercing fasteners are introduced into tissue to anchor the prosthesis.

Amended claim 23 defines a solution to a prior art problem; namely, the slippage of the prosthesis within the endovascular region after implantation and/or leakage of blood from an end of the prosthesis into the aneurism. Prior art solutions include the use of stents with tissue piercing barbs (see, e.g., Revelas US 5,968,053, listed on the attached Supplemented Information Disclosure Statement); staples or “rivets” (see, e.g., Dereume et al. US 5,639,278 – col. 7/7 to 14, listed on the attached Supplemented Information Disclosure Statement, or Taheri US 5,042,707, listed on the attached Supplemental Information Disclosure Statement); fasteners that are not tissue-piercing but are instead inserted through holes preformed in the vessel wall (see, e.g., Tanner et al US 5,944,750, listed on the attached Supplemental Information Disclosure Statement); and tissue piercing helical fasteners (see, e.g., Parodi US 6,336,933, listed on the attached Supplemented Information Disclosure Statement).

The endovascular delivery and implantation of tissue piercing fasteners posed their own technical problems. A fastener is desirably oriented for implantation at an angle with respect to the axis of the endovascular region itself. Prior art has addressed with this problem by bending or deflecting the fastener applier itself. See, e.g., Taheri ‘707, which steers the end of the fastener applier, or Parodi ‘933, which pre-bends the end of the fastener applier. Deflecting the fastener applier adds complexity to the overall assembly. One look at the articulated “stove pipe” assembly of Taheri ‘707 bears this out.

One aspect of the invention defined in amended claim 23 is directed to orienting the tissue piercing fastener with respect to a vessel wall without directly deflecting the fastener applier itself, but rather by providing a directing device having a deflectable distal end along which the fastener applier is introduced. Another aspect of the invention defined in amended claim 23 is directed to providing on the prosthesis itself a fastening region configured differently than the main body region for the receipt and retention in the second region of at least one tissue-piercing fastener implanted into tissue by an external fastener attachment assembly.

None of the prior art, either as listed in the Supplemental Information Disclosure Statement or as cited by the Examiner with respect to remaining claims 23 and 27 - Solovey (US5,769,884); Bolduc (US5,810,882); and Pinchuk (US 5,855,598) -- teaches or suggests a two component system,

as defined in amended claim 23, comprising an intraluminal directing device having a deflectable distal region and an intraluminal fastener applier separate from the directing device along which the fastener applier is introduced, which applies tissue piercing fasteners to a prosthesis that includes a fastening region configured differently than the main body region for the receipt and retention of at least one tissue-piercing fastener implanted into tissue by the external fastener attachment assembly.

For these reasons, applicant believes that Claims 23 and 27 to 30 are in condition for allowance. If the Examiner believes that questions or matters of clarification remain, applicant believes that such matters can be handled expeditiously by an interview by telephone to advance prosecution of this case, and the applicant is committed to proceed on that basis.

Respectfully Submitted,

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